

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK**

ANGELINE CACCHILLO,

Plaintiff,

vs.

**Civil Action No. 1:10-CV-01199
(TJM/RFT)**

INSMED INC.,

Defendant.

**THOMAS J. McAVOY,
Senior United States District Judge**

DECISION & ORDER

I. INTRODUCTION

Plaintiff commenced this action asserting claims pursuant to 42 U.S.C. §1983 and New York State common law following her participation in a phase II clinical trial of Defendant's investigational drug IPLEX™ ("IPLEX"). Defendant now moves to dismiss the action on various grounds. Plaintiff has opposed the motion.

II. BACKGROUND

The general background of this case has been set forth by this Court in its decision on Plaintiff's motion for a preliminary injunction, see Oct. 25, 2010 Dec. & Ord., dkt. # 23, and by the Second Circuit Court of Appeals in its review of the preliminary injunction decision. See Cacchillo v. Insmed, Inc., 638 F.3d 401 (2d Cir. 2011); see also May 11, 2011 Second Circuit Mandate, dkt. # 40. Familiarity with these opinions is presumed. Inasmuch as the matter is before the Court on a Rule 12 motion to dismiss, the following

facts are taken from the Complaint and deemed to be true for purposes of the pending motion.

Plaintiff Angeline Cacchillo, a New York resident, was diagnosed with Type 1 Myotonic Muscular Dystrophy ("MMD1" or "D1") in July 2005. MMD1 is a degenerative genetic neuromuscular disease which, in laymen's terms, attacks the muscles' ability to retract once contracted and, over time, attacks the muscles themselves including those necessary for the heart, brain, respiratory and digestive systems to function. There is no treatment for MMD1 approved by the Food and Drug Administration ("FDA").

Starting in November 2005, Insmed undertook a clinical trial to investigate the use of IPLEX for the treatment of MMD1 at the University of Rochester in Rochester, New York, a private research institution which receives public money as a National Institute of Health Center of Excellence for the treatment of, among other conditions, MMD1. In August 2007, while the initial phases of the MMD1 trial were ongoing, one of Mrs. Cacchillo's physicians contacted Ronald D. Gunn, the CEO of Insmed to ascertain whether she would be eligible to participate in the MMD1 trial. After determining that she would be eligible for the MMD1 trial, Gunn approached Dr. Richard Moxley, the chief investigator of Insmed's MMD1 trial at the University of Rochester, to secure Mrs. Cacchillo a place in the ongoing phases of the MMD1 clinical trial.

As Mrs. Cacchillo considered participating in the MMD1 trial, she and her husband, Robert Cacchillo, went to Insmed's website. The website included a number of messages from Insmed indicating that those who participated in clinical trials of IPLEX would enjoy Insmed's support in securing continued access to IPLEX if IPLEX proved to be safe and effective for them. This included a number of press releases discussing Insmed's support

for clinical trial subjects' efforts to secure continued IPLEX treatment, explanations of how patients could secure "compassionate use" of IPLEX through the FDA, and a link to the section of the FDA's website explaining how a clinical trial subject could apply for "compassionate use" of IPLEX.

After determining that Mrs. Cacchillo would be unable to enroll in the current phase of the MMD1 trial, Gunn directed Mrs. Cacchillo to contact Insmed's Clinical Study Manager Christine O'Neil so that O'Neil could have Mrs. Cacchillo enroll in Phase IIB of the MMD1 trial. O'Neil worked closely with Mrs. Cacchillo to match her up with one of the sites at which the upcoming Phase IIB of the MMD1 trial was to take place. O'Neil indicated to Mrs. Cacchillo that Insmed supported the efforts of clinical trial subjects to continue IPLEX treatment where it was shown to be safe and effective in treating individual subjects. O'Neil also worked closely with Mrs. Cacchillo in her applications to participate in Phase IIB of the MMD1 trial at both Ohio State University ("OSU") and the University of Rochester. Mrs. Cacchillo was accepted into the OSU study.

Mrs. Cacchillo went to OSU to meet with OSU's Clinical Research Coordinator Amy Bartlett on April 7, 2008. Neither O'Neil nor any other person ever explained to Mrs. Cacchillo the contours of OSU's legal relationship with Insmed. The close relationship between OSU and Insmed left Mrs. Cacchillo with the impression that they were partners in the MMD1 trial. The April 7 meeting was mandated by FDA regulation for the purpose of making clinical trial subjects aware of their rights and obligations as clinical trial subjects. During this meeting, Mrs. Cacchillo asked Mrs. Bartlett whether Insmed would assist her in continuing to receive IPLEX upon the conclusion of her participation in the MMD1 trial. Mrs. Bartlett assured Mrs. Cacchillo that Insmed would support Mrs. Cacchillo

in continuing IPLEX treatment if IPLEX was found to be safe and effective for her and that as a matter of custom, biopharmaceutical research companies like Insmmed supported such efforts.

Mrs. Cacchillo's participation in the MMD1 trial lasted from May 2008 to October 2008 and through it she experienced a near total recovery of her day-to-day functionality without suffering any side effects. Where she had once been able to withstand only a few minutes of light activity, had been unable to keep her chin from her chest without assistance, and could not dress herself, by October 2008, Mrs. Cacchillo was able to spend a day shopping, manipulate buttons and zippers, and walk with her head held up. This improvement was documented by Dr. Victoria Lawson, Assistant Professor of Neurology at OSU and the doctor who oversaw Mrs. Cacchillo's participation in the MMD1 trial, as well as Bartlett and Mrs. Cacchillo's personal physician, Dr. Peter Rienzi.

As Mrs. Cacchillo's participation in the MMD1 trial was ending in September 2008, Dr. Victoria Lawson approached Insmmed to confirm that IPLEX had been safe and effective for Mrs. Cacchillo and to secure Insmmed's support in either enrolling her in a new phase of the MMD1 trial or by providing a statement of support so that Dr. Lawson could submit Mrs. Cacchillo's compassionate use application to the FDA. Insmmed declined on the grounds that it was not clear whether Mrs. Cacchillo had received IPLEX or a placebo during the trial. Later, in July 2009, after it had been confirmed that Mrs. Cacchillo had been receiving IPLEX and not a placebo, Dr. Lawson again sought Insmmed's support for Mrs. Cacchillo's compassionate use application to the FDA. Insmmed again declined, this time because the MMD1 trial did "not allow for open label extension use" and regulations would "not allow [Insmmed] to set up a treatment IND without positive phase 2 results"

Plaintiff's suit, which seeks both equitable and legal relief, presents nine causes of action: (1) violation of her constitutional right to equal protection (seeking equitable relief and damages); (2) fraud (seeking damages); (3) negligent misrepresentation (seeking damages); (4) breach of contract (seeking equitable relief and damages); (5) intentional infliction of emotional distress (seeking damages); (6) assumption of duty (seeking equitable relief and damages); (7) breach of fiduciary duty (seeking equitable relief and damages); (8) negligence (seeking equitable relief and damages); and (9) unjust enrichment (seeking equitable relief and damages). Plaintiff also seeks attorneys fees and punitive damages.

III. DISCUSSION

a. Rule 12(b)(1) - Lack of Subject Matter Jurisdiction - Standing

Defendant argues that Plaintiff lacks constitutional standing to seek either equitable or legal relief in this matter. As the Second Circuit concluded, however, Plaintiff does have standing to seek "a specific document from Insmmed that she contends is required for her compassionate use application" and which Defendant allegedly promised to her. Cacchillo, 638 F.3d at 404. "[T]he court could redress Cacchillo's injury directly by ordering specific performance on the alleged underlying contract. That is, the court could redress Cacchillo's failure to receive the document from Insmmed by ordering Insmmed to provide her with the document." Id.; see also id. at 405 ("Based on the foregoing, Cacchillo has standing to pursue her motion for a preliminary injunction."). By the same reasoning, Cacchillo's injury could be redressed indirectly by an award of monetary damages under one of the theories on which she proceeds. Accordingly, Defendant's motion to dismiss

for lack of standing is denied.

b. Rule 12(b)(2) - Lack of Personal Jurisdiction

Defendant moves pursuant to Fed. R. Civ. P. 12(b)(2) to dismiss on the ground that the Court lacks personal jurisdiction over it. “A plaintiff bears the burden of demonstrating personal jurisdiction over a person or entity against whom it seeks to bring suit.” Penguin Group (USA) Inc. v. American Buddha, 609 F.3d 30, 34 (2d Cir. 2010)(citing In re Magnetic Audiotape Antitrust Litig., 334 F.3d 204, 206 (2d Cir. 2003) (*per curiam*)). In order to survive a motion to dismiss for lack of personal jurisdiction brought before discovery is conducted, as is the case here, “a plaintiff must make a *prima facie* showing that jurisdiction exists.” Thomas v. Ashcroft, 470 F.3d 491, 495 (2d Cir. 2006). “Such a showing entails making ‘legally sufficient allegations of jurisdiction,’ including ‘an averment of facts that, if credited[,] would suffice to establish jurisdiction over the defendant.’” Penguin Group, 609 F.3d at 34-35 (quoting In re Magnetic Audiotape, 334 F.3d at 206 (internal quotation marks and ellipsis omitted)). The Court is to accept all averments of jurisdictional facts as true, and construe the pleadings, affidavits, and any doubts in Plaintiff's favor. A.I. Trade Finance, Inc. v. Petra Bank, 989 F.2d 76, 79-80 (2d Cir. 1993); see also Marine Midland Bank, N.A. v. Miller, 664 F. 2d 899, 904 (2d Cir. 1981).

Defendant Insmed is a biopharmaceutical research company incorporated and headquartered in Virginia. “Personal jurisdiction of a federal court over a non-resident defendant is governed by the law of the state in which the court sits - subject, of course, to certain constitutional limitations of due process.” Robinson v. Overseas Military Sales Corp., 21 F.3d 502, 510 (2d Cir.1994); see Wiwa v. Royal Dutch Petroleum Co., 226 F.3d

88, 94 (2d Cir. 2000). Plaintiff asserts that personal jurisdiction over Defendant is obtained pursuant to New York's general jurisdictional statute contained at § 301 of the New York Civil Practice Laws and Rules ("CPLR § 301"), and pursuant to New York's long-arm jurisdiction statute contained at § 302(a) of the New York Civil Practice Laws and Rules ("CPLR § 302(a)").

1. General Jurisdiction - CPLR § 301

"[A] foreign corporation is subject to general personal jurisdiction in New York [under CPLR § 301] if it is 'doing business' in the state." Wiwa, 226 F.3d at 95 (citing CPLR § 301). A corporation does business in New York for purposes of CPLR § 301 "if it is engaged in such a continuous and systematic course of 'doing business' in the state as to warrant a finding of . . . 'presence' in this jurisdiction." Welinsky v. Resort of the World D.N.V., 839 F.2d 928, 929 (2d Cir. 1988)(ellipsis in original)(alteration omitted). Put another way, "a corporation is 'doing business' and is therefore 'present' in New York and subject to personal jurisdiction with respect to any cause of action, related or unrelated to the New York contacts, if it does business in New York not occasionally or casually, but with a fair measure of permanence and continuity." Wiwa, 226 F.3d at 95 (internal citation and quotation marks omitted); see Landoil Res. Corp. v. Alexander & Alexander Serv. Inc., 918 F.2d 1039 (2d Cir.1990).

"New York courts have focused on several factors to support a finding that a defendant was 'doing business,' including 'the existence of an office in New York; the solicitation of business in New York; the presence of bank accounts or other property in New York; and the presence of employees or agents in New York.'" Xiu Feng Li v. Hock, 371 Fed. Appx. 171, 2010 WL 1193446, at * 2 (2d Cir. March 30, 2010)(quoting Landoil,

918 F.2d at 1043). When considering whether a foreign corporation is present in a state, a court must take into account the nature of the defendant's business and assess its contacts in this context. See Ivoclar Vivadent, Inc. v. Hasel, 2003 WL 21730520, at *3 - *4 (W.D.N.Y. 2003);¹ Capitol Records v. Optical Recording Corp., 810 F. Supp. 1350, 1352-53 (S.D.N.Y. 1992). In this regard, the Court must consider whether the defendant's transaction of business in New York, whether itself or through an agent, constitutes the continuous and systematic activity of the important functions of the defendant's business. See Wiwa, 226 F.3d at 95;² Ivoclar Vivadent, 2003 WL 21730520, at *3; Capitol Records, 810 F. Supp. at 1353.³

"[F]or a corporation to be considered an agent . . . for personal jurisdiction purposes, a plaintiff must allege: (1) that the corporation engaged in purposeful activities in New York in relation to the transaction; (2) that the corporation's activities were performed for the benefit of the individual defendant; (3) that the corporation's activities were performed with the knowledge and consent of the individual defendant; and (4) that the individual defendant exercised some control over the corporation." Beatie & Osborn

¹("Initially, it is important to note that [defendant's] sole function is to manage, enforce and license its patents and that it lacks the traditional indicia of doing business because it does not manufacture or sell tangible goods. Accordingly, the frequency and nature of [defendant's] New York business activities must be analyzed within such a context in determining whether such contacts demonstrate the requisite degree of permanence.")(interior quotation marks and citation omitted)

²("Under well-established New York law, a court of New York may assert jurisdiction over a foreign corporation when it affiliates itself with a New York representative entity and that New York representative renders services on behalf of the foreign corporation that go beyond mere solicitation and are sufficiently important to the foreign entity that the corporation itself would perform equivalent services if no agent were available.")

³(noting that, for the purposes of establishing personal jurisdiction, a company's business activities conducted in New York must not be peripheral to its "main business" but must be a substantial part of that corporation's business)

LLP v. Patriot Sci. Corp., 431 F. Supp.2d 367, 389 (S.D.N.Y.2006). Moreover, “[t]he agent must be primarily employed by the defendant and not engaged in similar services for other clients.” Wiwa, 226 F.3d at 95.

In assessing whether a defendants' contacts with New York are sufficient to establish general jurisdiction, the relevant question is whether the defendant was present in New York at the time the complaint was filed. To the extent that events occurring prior to that time are relevant, it is only to establish the pattern of contacts that existed at the moment the complaint was filed.

Duravest, Inc. v. Viscardi, A.G., 581 F. Supp.2d 628, 638 (S.D.N.Y. 2008)(citations and quotation marks omitted).

Plaintiff asserts through her affidavits, pleadings, and other evidence that Defendant Insmed owns the exclusive right to manufacture and distribute IPLEX, a drug Insmed developed in close partnership with the National Institutes of Health ("NIH") and a number of public hospitals and research institutions throughout the United States. Plaintiff further asserts that Insmed's rights to IPLEX and the research Insmed has conducted are Insmed's sole pharmaceutical asset and make up the bulk of Insmed's value as company. Also, in direct contravention to Defendant's prior assertion that it no longer manufactures IPLEX and that the remaining supplies of the drug have been allocated to certain Amyotrophic Lateral Sclerosis ("ALS") patients in this Country and Italy, Plaintiff has presented evidence demonstrating that since June 2010 Insmed has represented to the Securities and Exchange Commission that it is providing IPLEX for a clinical trial in Sweden to investigate the use of IPLEX for the treatment of Retinopathy of Prematurity ("ROP"). See R. Cacchillo Aff. ¶ 13. Plaintiff asserts that Defendant retains the right to manufacture and distribute IPLEX and may do so through a third-party. Compl. ¶ 67.

As to its contacts with New York, Plaintiff asserts that of the five (5) clinical trials

Insmmed has sponsored or collaborated in since 2005 for the development of IPLEX, four (4) were conducted in whole or in part in New York. Plaintiff further argues that most of the data for the commercial use of IPLEX was generated at the University of Rochester, “where Insmmed invested millions of dollars to generate data on IPLEX as a treatment for [Type 1 Myotonic Muscular Dystrophy (“MMD1” or “D1”).” PI. MOL, p. 10 (citing Cacchillo Aff., Ex. A, p. 4).⁴ Moreover, Plaintiff asserts that Insmmed conducted clinical trials that took place, in part, in New York to investigate the use of IPLEX for the treatment of Noonan's Syndrome, and sponsored a clinical trial to test the use of IPLEX for the treatment of Growth Hormone Insensitivity Syndrome and Laron Syndrome conducted by, *inter alia*, Dr. Robert Rapaport, a doctor practicing at the Mount Sinai Medical Center in New York City. See Luibrand Aff. ¶ 12 and exhibits cited thereat. Plaintiff contends that this last trial was on-going as late as December 2010, after Plaintiff commenced this action. Plaintiff also contends that Defendant used the University of Rochester to recruit trial participants, including many New York residents, for clinical trials that were conducted outside New York. Plaintiff further contends that Defendant maintained an Internet website which was visible in New York and which was successful in inducing New York residents such as Plaintiff to voluntarily participate in one of Defendant's clinical trials.

Plaintiff argues that because Insmmed is a biopharmaceutical research company

⁴The Court presumes that the citation is to Exhibit A attached to Robert Cacchillo's 12/17/10 affidavit inasmuch as there are no exhibits attached to Angeline Cacchillo's affidavit submitted on this motion. Exhibit A to Robert Cacchillo's 12/17/10 affidavit is a print out of a portion of Insmmed's website which indicates, *inter alia*, that “[w]ith funding provided by the Muscular Dystrophy Association and the National Institute of Health, Insmmed is conducting a randomized, placebo-controlled, double-blind clinical study in 60 patients with MMD.” The exhibit does not indicate that the study is at the University of Rochester, although that fact can be gleaned from the other facts in the case. The exhibit also does not indicate the amount of money invested in the clinical study although it could be reasonably concluded that such a study would be expensive to conduct.

whose only asset is its right to manufacture a single drug that it is not yet legally allowed to sell, it cannot depend on traditional income to fund its operations. Instead, Plaintiff contends, Insmmed needs to generate investments to cover operating costs through investors who would not expect a return until IPLEX had become profitable. In this regard, Plaintiff asserts that Insmmed sought out this revenue through the New York City offices of FD, an investor relations firm. According to Plaintiff, all of Insmmed's investor relations activities were conducted through these offices, as all investment-related inquiries made to Insmmed were referred to an agent in these New York offices.

Defendant contests the factual bases of Plaintiff's CPLR § 301 arguments.⁵

⁵Defendant asserts:

The studies identified by plaintiff were conducted long before she filed her Complaint. The Noonan Syndrome study began July 11, 2006, and was terminated on March 29, 2007. The GHIS study began on or about August 23, 2006. No patients have been enrolled at the New York site. The first DM1 study, conducted at the University of Rochester, began in November 2005, and ended in May 2008, two years before plaintiff filed her Complaint. Moreover, Insmmed did not initiate or sponsor this trial, and none of its employees acted as investigators. Insmmed provided the drug to the sponsor at no charge, and was not otherwise involved in the trial. The second DM1 study began December 18, 2007 and ended around March 2009, over one year before plaintiff filed her Complaint. Only one New York resident enrolled in that study, and that person received his final dose on December 8, 2008.

. . . [P]laintiff [mistakenly] declares that these drug trials represented the "core" of Insmmed's business activities even though until March 2009, Insmmed owned and operated a \$130 million follow-on biologics business located in Colorado. There is no basis for plaintiff's conclusion that four drug trials involving only a few New York residents that ended before or by March 2009, were the "core" of Insmmed's business at the time she filed her Complaint.

Insmmed's contractual relationship with the New York City office of an international public relations firm similarly does not establish this Court's jurisdiction. . . . [P]laintiff merely alleges that Insmmed has a contractual relationship with the New York office of an international public relations firm. She does not and cannot allege that the firm is "primarily employed" by Insmmed or an agent of Insmmed, and therefore general jurisdiction cannot be predicated on the firm's New York activities.

Plaintiff's reference to Insmmed's passive website that is visible in New York also is insufficient to confer general jurisdiction. Plaintiff has not and cannot allege that the website somehow targeted New York consumers.

Def. Reply MOL, pp. 3-5 (citations omitted). Defendant does not contest, however, that it has been supplying
(continued...)

Plaintiff's allegations, when taken together, accepted as true, construed in the light most favorable to Plaintiff, and viewed in the context of Defendant's business as Plaintiff portray's it to be, establish a *prima facie* case that Defendant was doing business in New York for purposes of CPLR § 301. Inasmuch as Plaintiff portrays Defendant as a pharmaceutical research company that has tested the commercial viability of it is only product primarily through New York research institutes using New York residents,⁶ that it has done so with a fair degree of continuity, that at the time of commencement of this action it continued to engaged in clinical trials for the commercial use of IPLEX conducted, at least partially, in New York, and that the sole means of funding Defendant's research has been conducted through an investors relations agent working in an office in New York City,⁷ the Court denies the motion on this ground. Defendant may renew the motion at a later time. See Marine Midland Bank, 664 F. 2d at 904.⁸

2. Specific Jurisdiction - CPLR § 302(a)

Plaintiff also asserts that the Court may assert personal jurisdiction over Defendant pursuant to CPLR §§ 302(a)(1) and (a)(3).

⁵(...continued)

IPLEX to a clinical trial in Sweden.

⁶The Court notes that "solicitation of business alone will not justify a finding of corporate presence in New York," Xiu Feng Li v. Hock, 371 Fed. Appx. 171, 174 (2d Cir. 2010), and "the fact that a foreign corporation has a website accessible in New York is insufficient to confer jurisdiction under CPLR § 301." Spencer Trask Ventures v. Archos S.A., 2002 WL 417192, at *6 (S.D.N.Y. Mar. 18, 2002).

⁷The facts, viewed in the light most favorable to Plaintiff, could lead to the conclusion that Defendant exercised control over the investor relations agent. However, whether the agent was primarily employed by the defendant and not engaged in similar services for other clients is unclear.

⁸("Eventually, . . . the plaintiff must establish [personal] jurisdiction by a preponderance of the evidence, either at a pretrial evidentiary hearing or at trial.")

A. CPLR § 302(a)(1)

Under CPLR § 302(a)(1), a court may assert specific personal jurisdiction over a foreign corporation if the defendant “transacts . . . business” within the state and the claim against the defendant “aris[es] from” activity within New York. See CPLR § 302(a)(1); McGowan v. Smith, 52 N.Y.2d 268, 271 (1981). “CPLR 302(a)(1) jurisdiction is proper ‘even though the defendant never enters New York, so long as the defendant's activities here were purposeful and there is a substantial relationship between the transaction and the claim asserted.’” Fischbarg v. Doucet, 9 N.Y.3d 375, 380 (2007) (quoting Deutsche Bank Sec., Inc. v. Montana Bd. of Invs., 7 N.Y.3d 65, 71 (2006)). “Purposeful activities are those with which a defendant, through volitional acts, ‘avails itself of the privilege of conducting activities within the forum State, thus invoking the benefits and protections of its laws.’” Fischbarg, 9 N.Y.3d at 380 (quoting McKee Elec. Co. v. Rauland-Borg Corp., 20 N.Y.2d 377, 382 (1967)); see Ehrenfeld v. Mahfouz, 489 F.3d 542, 548 (2d Cir. 2007).⁹

A claim “arises from” a transaction where it bears “an articulable nexus, or a substantial nexus” between the claim and the transaction. Henderson v. INS, 157 F.3d 106, 123 (2d Cir. 1998); see Grand River Enterprises Six Nations, Ltd. v. Pryor, 425 F.3d 158, 166 (2d Cir. 2005). “It is well-settled that CPLR 302(a)(1) is a ‘single-act’ statute, meaning that ‘proof of one transaction in New York is sufficient to invoke jurisdiction [under 302(a)(1)], even though the defendant never enter[ed] New York’” Salomon Smith Barney, Inc. v. McDonnell, 201 F.R.D. 297, 303 (S.D.N.Y. 2001)(quoting PDK Labs, Inc. v. Friedlander, 103 F.3d 1105, 1109 (2d Cir.1997), in turn citing Kreutter v. McFadden

⁹(“A non-domiciliary transacts business in New York by purposefully availing him or herself of the privilege of conducting activities within the State, thus invoking the benefits and protections of its laws.”)(internal quotation marks and alterations omitted)

Oil Corp., 71 N.Y.2d 460, 467(1988)).

Plaintiff argues that “[a]ll of Mrs. Cacchillo's claims arise out of Insmmed's sponsorship of the MMD1 trial in New York and its activities pertaining to it.” Pl. MOL. p. 18. In this regard, Plaintiff contends that Insmmed CEO Ronald Gunn approached Dr. Moxley of the University of Rochester about securing Mrs. Cacchillo a place in the MMD1 trial, Compl. ¶ 119, and that Gunn then had Insmmed's Study Manager O'Neil contact Mrs. Cacchillo in New York to solicit her participation in the MMD1 trial. Compl. ¶ 121. Plaintiff argues that, even though she was enrolled in that portion of the MMD1 trial conducted at OSU, Defendant was aware that Plaintiff would be substantially participating in the trial from New York. In this regard, Plaintiff was provided IPLEX by Insmmed so that she could take it on a daily basis while in New York. Moreover, while she was at her home in New York, she was required to monitor her blood sugar and any side effects from the daily injections, and she was required to wear an activity monitoring device so that effects of the drug could be evaluated. Compl. ¶¶ 147-48; 2d Cacchillo Aff. 14-16, 20. During the trial, Plaintiff also recorded other results of her IPLEX treatment while in New York and related these results to Study Manager O'Neil, who provided Plaintiff with encouragement and assistance during the course of Plaintiff's participation. Cacchillo Aff. ¶¶ 27, 58. Again, Defendant challenges the factual bases of Plaintiff's contentions.¹⁰

Taking the allegations in the light most favorable to the Plaintiff and treating the

¹⁰Defendant asserts that: (1) Insmmed did not sponsor the first MMD1 trial at the University of Rochester; (2) none of Insmmed's employees served as investigators for the trial; (3) Insmmed merely supplied IPLEX to the sponsor at no charge; and (4) Insmmed did not otherwise participate in the trial. Moreover, Defendant argues that Plaintiff's claims all arise from the MMD1 trial conducted by Ohio State University. On this last point, Defendant argues that the conversation between Insmmed's former CEO contacted Dr. Moxley at the University of Rochester about securing Plaintiff a place in the Phase I and II trials being conducted in Ohio and is wholly unrelated to any contact that Defendant had in New York.

jurisdictional assertions as true, Plaintiff may be able to satisfy both prongs of the Section 302(a)(1) analysis. That is, if the facts are as discussed above with regard to the §301 analysis, then Plaintiff may be able to establish that Defendant transacted business in New York in the form of clinical research of IPLEX (both through the various clinical trials and through Plaintiff's recordings of the effects her own clinical trial participation) and the solicitation of clinical trial participants. See Freidman v. Schwartz, 2009 WL 701111, at *3 (E.D.N.Y. March 13, 2009).¹¹ Further, and assuming *arguendo* that there is a connection between the Rochester and Ohio clinical trials, Plaintiff could establish that her claims arose from this transaction of business. While it may well be that the facts will demonstrate that the OSU clinical trial was completely separate from the New York trials, that all pertinent contacts that Plaintiff had with Defendant (or its agents) took place outside of New York, see Chong v. Healthtronics, Inc., 2007 WL 1836831, at *9 (E.D.N.Y. June 20, 2007);¹² Tyco Intern. Ltd. v. Walsh, 2003 WL 553580, at *4 (S.D.N.Y. Feb. 27, 2003),¹³ and that the only connection to New York is that New York is the place of Plaintiff's residence where she took the experimental IPLEX and monitored its affects between her visits to Ohio. However, these facts must be developed through discovery.

¹¹("The 'transacting business' test under C.P.L.R. § 302(a)(1) requires the purposeful availment of the privilege of conducting activities within New York, thus invoking the benefits and protections of its laws, not regular and systematic activities like the 'doing business' standard required for general jurisdiction.")

¹²("[D]efendant's use of telephone, facsimiles or e-mails to communicate with plaintiff in New York are insufficient to establish that defendant transacted business in New York, absent any indication that defendant intended to project itself into ongoing New York commerce.")(interior quotation marks and citation omitted).

¹³("Generally, telephone contacts between a nondomiciliary defendant and a New York party are insufficient by themselves to confer jurisdiction under Section 302(a)(1). Fiedler v. First City Nat'l Bank, 807 F.2d 315, 317-18 (2d Cir.1986). A nondomiciliary defendant will be subject to jurisdiction under Section 302(a)(1), however, if the defendant uses these telephone communications to deliberately "project" himself into business transactions occurring within the State. See Parke-Bernet Galleries, Inc. v. Franklyn, 26 N.Y.2d 13, 18, 308 N.Y.S.2d 337, 256 N.E.2d 506 (1970) (defendant projected himself into art auction in State by participating in bidding by telephone).")

Accordingly, the motion to dismiss on this ground is denied.

B. CPLR § 302(a)(3)

Plaintiff also asserts specific jurisdiction under CPLR § 302(a)(3). CPLR § 302(a)(3) requires a showing that Defendant committed a tortious act outside the state causing injury to a person or property within the state, and that Defendant

(i) regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered, in the state,

or

(ii) expects or should reasonably expect the act to have consequences in the state and derives substantial revenue from interstate or international commerce.

CPLR § 302(a)(3)(i), (ii).

To determine whether there was a tortious act outside the state causing injury within the state, courts "must generally apply a situs-of-injury test which asks them to locate the original event which caused the injury." Whitaker v. Am. Telecasting, Inc., 261 F.3d 196, 209 (2d Cir. 2001)(internal quotation and citation omitted). "[T]he situs of injury for purposes of asserting long arm jurisdiction is the place where the underlying, original event occurred which caused the injury." Id. "This 'original event' is, however, generally distinguished not only from the initial tort but from the final economic injury and the felt consequences of the tort." Bank Brussels Lambert v. Fiddler Gonzalez & Rodriguez, 171 F.3d 779, 791 (2d Cir.1999). As the Second Circuit has explained, "[t]he situs of the injury is the location of the original event which caused the injury, not the location where the resultant damages are felt by the plaintiff." Whitaker, 261 F.3d at 209 (internal quotation marks and citation omitted). "[T]he residence of the injured party in New York is not

sufficient to satisfy the clear statutory requirement of an 'injury within the state.'" McGowan v. Smith, 52 N.Y.2d 268, 274-75 (1981).

Plaintiff argues that her tort injury was caused by a succession of events, only a few of which occurred outside of New York. In this regard, she contends that she was approached by Insmmed CEO Gunn and Study Manager O'Neil by phone while she was in New York, that she viewed Insmmed's internet website representations regarding Defendant's support for compassionate use applications while in New York, R. Cacchillo Aff., ¶¶ 2-4, and that she was convinced to enroll in the MMD1 trial by Insmmed's agents while she was in New York. Compl. ¶ 126; Cacchillo Aff. ¶ 27. She further argues that she participated in the clinical trial in New York where she took the IPLEX, recorded her daily condition while on the drug, wore a monitoring device, and reported back to OSU and Insmmed with the results. Cacchillo Aff. ¶ 58; 2d Cacchillo Aff. ¶¶ 14-16. Plaintiff asserts that Defendant was aware of her residence and where she was taking the IPLEX because Insmmed partly financed her trips to and from Schenectady, New York and OSU. Compl. ¶ 149. Moreover, Plaintiff contends that when Insmmed made its decision to not support her compassionate use application, it was communicated to her while she was in New York. Cacchillo Aff. Exhibit E. In this regard, Plaintiff asserts that "[w]hile the most explicit misrepresentation to Mrs. Cacchillo was made during April 7, 2008 meeting with Amy Bartlett at OSU, every other misrepresentation was directed by Insmmed to Mrs. Cacchillo in New York and was received by her and relied upon by her while she was in New York." Plf. MOL pp 19-20 (citing Compl. ¶¶ 121-23, 141).

Assuming these facts to be true, and assuming (as discussed above) that Defendant regularly does or solicits business, or engages in any other persistent course of

conduct, in New York by way of its clinical trials and other research conducted within the State, then Plaintiff may be able to establish jurisdiction under CPLR § 302(a)(3)(i). Thus, she has made a *prima facie* showing sufficient to survive the instant motion in this regard.

“Under CPLR § 302(a)(3)(ii), jurisdiction is proper only if: (1) the defendant has committed a tortious act outside of New York, (2) the cause of action arises out of that tortious act, (3) the act must have caused injury to a person or property within New York; (4) the defendant expected or reasonably should have expected the act to have consequences in New York, and (5) the defendant derives substantial revenue from interstate or international commerce.” JP Morgan Chase Bank, N.A. v. Law Office of Robert Jay Gumenick, P. C., 2011 WL 1796298, at *5 (S.D.N.Y., April 22, 2011) .

Although hotly contested by Insmmed, Plaintiff contends that Insmmed's allocation of IPLEX to ALS patients in the United States and Italy “generates substantial revenue for Insmmed as Insmmed is compensated for that IPLEX it administers to ALS patients.” PI. MOL p. 20 (citing Compl. ¶¶ 48-49, 71). Assuming that Plaintiff can establish that Defendant derives substantial revenue from interstate or international commerce, and assuming that Plaintiff can establish the other facts as discussed above, Plaintiff may be able to satisfy CPLR § 302(a)(3)(ii). Again, she has made a *prima facie* showing sufficient to survive the instant motion in this regard

2. Due Process

Plaintiff must also demonstrate that the exercise of jurisdiction would be consistent with federal due process requirements. Wiwa, 226 F.3d at 99. To satisfy the requirements of due process, a plaintiff must first show first that the defendant has “certain minimum contacts with [the forum state] such that the maintenance of the suit does not offend

traditional notions of fair play and substantial justice.” Int’l Shoe Co. v. Washington, 326 U.S. 310, 316 (1945)(interior quotation marks and citation omitted). “Where specific jurisdiction is found, minimum contacts exist ‘where the defendant purposefully availed itself of the privilege of doing business in the forum and could foresee being haled into court there,’ but where general jurisdiction is found, minimum contacts exist only where the contacts ‘are continuous and systematic.’” Chong, 2007 WL 1836831, at *10 (quoting Bank Brussels Lambert v. Fiddler Gonzalez & Rodriguez, 305 F.3d 120, 127 (2d Cir. 2002)(internal quotations and citations omitted)). The exercise of jurisdiction is favored where the plaintiff has made a threshold showing of minimum contacts at the first stage of the inquiry, but it may be defeated where the defendant presents “a compelling case that the presence of some other considerations would render jurisdiction unreasonable.” Burger King Corp. v. Rudzewicz, 471 U.S. 462, 477 (1985).

Assuming that circumstances were as Plaintiff asserts - that is, that a large majority of Defendant’s research endeavors for its only product are conducted through New York institutions using predominantly New York residents, that Plaintiff and other clinical participants were solicited in New York, that Plaintiff substantially participated in the MMD1 trial while in New York, and that all of Defendant’s funding and investments are conducted through its New York agent, due process is satisfied at this stage. Defendant may renew its motion in this regard at a later time. Accordingly, Defendant’s motion under Rule 12(b)(2) is denied.

c. Rule 12(b)(7) - Failure to Join the FDA

Defendant’s argument that the FDA is an indispensable party is without merit. As the Second Circuit concluded, “Cacchillo’s injury in fact is that in breach of an alleged

agreement between herself and Insmmed, she has not received Insmmed's support in preparing her compassionate use application." Cacchillo, 638 F.3d at 404. "This injury is actual, and not conjectural or hypothetical, because Cacchillo does not have the document to which she currently claims entitlement." Id. Whether Plaintiff will be successful before the FDA *if* she receives the document is irrelevant to redressing her injury in fact. Id. ("Insmmed's lack of support is no less an injury because Cacchillo additionally hopes to receive both Insmmed's support and, ultimately, FDA approval."). The failure to join the FDA does not prevent the Court from affording complete relief among the existing parties, nor does it subject Defendant from incurring multiple or inconsistent obligations. Accordingly, the FDA is not an indispensable party and Defendant's motion on this ground is denied.

d. Rule 12(b)(6) - Failure to State a Claim Upon which Relief Can be Granted

Defendant moves pursuant to Rule 12(b)(6) to dismiss Plaintiff's claims. The Court will apply the Rule 12(b)(6) standard of review set forth by the Supreme Court in Ashcroft v. Iqbal, —U.S. —, 129 S. Ct. 1937, 173 L. Ed.2d 868 (2009), Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 127 S. Ct. 1955, 167 L. Ed.2d 929 (2007), and their progeny. See Savatxath v. Stoeckel, 2011 WL 1790159, at *1 (N.D.N.Y. May 10, 2011)(discussing this standard of review).

1. § 1983/ Bivens Claim

Plaintiff's First Cause of Action asserts that her constitutional rights, including her right to equal treatment under law, were deprived by Defendant's actions in failing to support her compassionate use application for IPLEX while supporting compassionate use

of IPLEX for ALS patients. Compl. ¶¶ 161-64, 170-86,192. Although the claim is asserted under the title "Violation of Civil Rights Pursuant to 42 U.S.C. § 1983," Compl. ¶¶ 191-94, an introductory paragraph in the Complaint asserts that Plaintiff brings claims under § 1983 and Bivens v. Six Unknown Agents of the Federal Bureau of Narcotics, 403 U.S. 388 (1971). Compl. ¶ 2.

To implicate 42 U.S.C. § 1983, the Defendant's conduct must be "fairly attributable to the State." Lugar v. Edmondson Oil Co., 457 U.S. 922, 937 (1982); see also Brentwood Academy v. Tenn. Secondary Sch. Ath. Ass'n, 531 U.S. 288, 306 (2001). Although the courts use "many different tests to identify state action, they all have a common purpose. Our goal in every case is to determine whether an action can fairly be attributed to the State." Brentwood Academy, 531 U.S. at 306; see Sybaliski v. Independent Group Home Living Program, Inc., 546 F.3d 255, 257-58 (2d Cir. 2008).¹⁴ The same analysis applies in determining whether action by a private entity was taken "under color of federal law." Island Online, Inc. v. Network Solutions, Inc., 119 F. Supp.2d 289, 304 (E.D.N.Y., 2000).

To demonstrate that Defendant's actions could be attributed to the state or federal government, Plaintiff alleges that Insmed collaborated with the NIH during the MMD1 trial, Compl. ¶ 99, that the MMD1 trial was conducted at specific state funded public research hospitals or at NIH Centers of Excellence, Compl. ¶¶ 100-01, that IPLEX's development

¹⁴In Sybaliski, the Second Circuit explained:

[T]he actions of a nominally private entity are attributable to the state when: (1) the entity acts pursuant to the "coercive power" of the state or is "controlled" by the state ("the compulsion test"); (2) when the state provides "significant encouragement" to the entity, the entity is a "willful participant in joint activity with the [s]tate," or the entity's functions are "entwined" with state policies ("the joint action test" or "close nexus test"); or (3) when the entity "has been delegated a public function by the [s]tate," ("the public function test").

546 F.3d at 257-58.

for market was done in close collaboration with the NIH and FDA, and that the FDA had granted Insmmed tax breaks and funding for the purpose of developing IPLEX. Compl. ¶¶ 33, 73-88, 90-93. Such allegations, however, are insufficient.

"It is not enough . . . for a plaintiff to plead state involvement in *some activity* of the institution alleged to have inflicted injury upon a plaintiff; rather, the plaintiff must allege that the state was involved with *the activity that caused the injury* giving rise to the action." Sybalski, 546 F.3d at 257-58 (internal quotation marks and citation omitted)(emphasis in Sybalski); see also United States v. Int'l Bhd. of Teamsters, 941 F.2d 1292, 1296 (2d Cir.1991).¹⁵ Here, there are no allegations that any federal or state agency or actor had any involvement in Insmmed's decision to decline its support for Plaintiff's compassionate use application. Because this decision forms the underpinning of Plaintiff's claims, there is no plausible basis upon which to find state or federal action sufficient to support a § 1983 or a Bivens claim. Accordingly, the First Cause of Action is dismissed.

2. Fraud

Plaintiff's second cause of action asserts a claim of fraudulent inducement. Compl. ¶ 196. Under New York law, the five elements of a fraud claim are: "(1) a material misrepresentation or omission of fact; (2) made by defendant with knowledge of its falsity (3) an intent to defraud; (4) reasonable reliance on the part of the plaintiff; and (5) resulting damage to the plaintiff." Crigger v. Fahnestock & Co., 443 F.3d 230, 234 (2d Cir. 2006). "The elements of a cause of action for fraud in the inducement are the same as those for fraudulent misrepresentation, namely representation of a material existing fact, falsity,

¹⁵("The question is not whether the decision to establish the [private entity] was state action, but rather whether the [private entity]'s decision to sanction [plaintiffs] may be 'fairly attributable' to the [g]overnment.")(citing Lugar, 457 U.S. at 937)

scienter, reliance, and injury.” Twin Holdings of Delaware LLC v. CW Capital, LLC, 26 Misc.3d 1214(A), 906 N.Y.S.2d 784 (Table), 2010 WL 309022, at *9 (N.Y. Sup. Nassau Cty., Jan. 19, 2010)(citing Urstadt Biddle Properties v. Excelsior Realty Corp., 65 A.D. 3d 1135 (2nd Dept. 2009)); see Cohen v. Koenig, 25 F.3d 1168, 1172 (2d Cir. 1994);¹⁶ Levin v. Gallery 63 Antiques Corp., 2006 WL 2802008, at * 6 (S.D.N.Y. Sept. 26, 2006).¹⁷

Plaintiff alleges that Insmmed represented through its website, Study Manager O'Neil, and OSU's Bartlett that, in return for her MMD1 trial participation, Insmmed would support her compassionate use application at the end of the clinical trial if IPLEX proved to be safe and effective for her. Compl. ¶¶ 125-26, 129-30, 141-44. Plaintiff alleges that even though IPLEX proved to be safe and effective for her, Compl. ¶¶ 22, 116, 130, 141-43, 151, Insmmed declined its support for her compassionate use application. She asserts that the statements about Insmmed supporting a compassionate use application were knowingly false when made because Insmmed had settled of a prior patent infringement lawsuit which limited IPLEX's compassionate use for patients with ALS. See Compl. ¶¶ 155-60. Plaintiff further asserts that it was reasonable for her to rely on Defendant's representations because of Insmmed's expertise with IPLEX and FDA regulations, and because of Insmmed's acts of intentionally leading her to believe that it had her best interests at heart. Compl. ¶¶ 119, 125, 130. Plaintiff contends she was damaged by this fraud in that she was induced

¹⁶(“To prevail on a fraudulent misrepresentation claim under New York law, . . . a plaintiff must show (1) that [the defendant] made a misrepresentation (2) as to a material fact (3) which was false (4) and known to be false by [the defendant] (5) that was made for the purpose of inducing [the plaintiff] to rely on it (6) that [the plaintiff] rightfully did so rely (7) in ignorance of its falsity (8) to his injury.”)(internal quotation marks and citations omitted).

¹⁷(“To state a claim for fraud under New York law, [Plaintiff] must demonstrate: (i) a representation of material fact; (ii) falsity; (iii) scienter; (iv) reasonable reliance; and (v) injury. To plead fraudulent misrepresentation [Plaintiff] must likewise allege that [it] reasonably relied on false representations made by Defendant[.]”)(citations omitted).

to participate in the clinical trial whereby she took IPLEX experiencing positive results while on the drug but also experiencing severe withdrawal exacerbation of her symptoms beyond her pre-trial condition when taken off of the drug at the end of the trial. Compl. ¶¶ 16, 117, 168-73. This, she asserts, caused her to sufferer emotional distress and pain due to her physical deterioration. She also contends that the fraudulent misrepresentation about Inmed supporting compassionate use applications induced her to participate in the trial which, in turn, cost her various expenses involved in traveling to and from the study site. Compl. ¶¶ 24, 117, 148, 197.

These allegations are sufficient to state a *prima facie* case of fraudulent inducement. Defendant's motion to dismiss this claim is denied.

3. Negligent Misrepresentation

Plaintiff's Third Cause of Action alleges a claim of negligent misrepresentation arising out of Defendant's representations that it would support her efforts to secure continued access to IPLEX if it were proven safe and effective for her. "Under New York law, the elements for a negligent misrepresentation claim are that (1) the defendant had a duty, as a result of a special relationship, to give correct information; (2) the defendant made a false representation that [it] should have known was incorrect; (3) the information supplied in the representation was known by the defendant to be desired by the plaintiff for a serious purpose; (4) the plaintiff intended to rely and act upon it; and (5) the plaintiff reasonably relied on it to his or her detriment." Hydro Investors, Inc. v. Trafalgar Power Inc., 227 F.3d 8, 20 (2d Cir. 2000) (citations omitted).

Defendant challenges this claim on the first element. "Liability for negligent misrepresentation may be imposed 'only on those persons who possess unique or

specialized expertise, or who are in a special position of confidence and trust with the injured party such that reliance on the negligent misrepresentation is justified.”

Amusement Industry, Inc. v. Stern, — F. Supp.2d ----, 2011 WL 867274 (S.D.N.Y. March 11, 2011)(quoting Kimmell v. Schaefer, 89 N.Y.2d 257, 263 (1996)). “[T]he existence of a special relationship is a ‘fact-intensive, case-by-case inquiry. . . .’” Id. (quoting In re Vivendi Universal, S.A., 2004 WL 876050, at *13 (S.D.N.Y. Apr. 22, 2004)).

The facts as alleged in the Complaint adequately plead that Defendant was possessed of unique or specialized expertise in the areas of IPLEX administration and compliance with FDA compassionate use regulations, and that Defendant was in a special position of confidence and trust with Plaintiff as a prospective IPLEX trial participant suffering from MMD1. While the facts may reveal that the structure of the clinical trial in which Plaintiff participated excluded Defendant, as the sponsor of the trial, from falling within a "position of confidence and trust" requiring it to give correct information about IPLEX administration or post-trial treatment options, the allegations in the Complaint are sufficient to establish that Defendant was in such a position regarding Insmmed’s own policy and intentions for FDA compassionate use applications by or for IPLEX clinical trial participants.

Moreover, the Complaint adequately alleges that Plaintiff questioned whether Defendant would support her compassionate use application when she was deciding whether to participate in the clinical trial; that she reasonably relied on Defendant’s representations that it would support her compassionate use application in deciding to enter the trial; and that she suffered detriment from participating in the trial by virtue of her IPLEX withdrawal exacerbations. These allegations are sufficient to state a *prima facie*

claim of negligent misrepresentation. Accordingly, Defendant's motion to dismiss this claim is denied.

4. Breach of Contract

Plaintiff's Fourth Cause of Action asserts a claim of breach of contract. Compl. ¶¶ 201-03. Plaintiff seeks specific performance and/or monetary damages. See Compl. Demand for Relief, ¶ d, p. 27. To set forth a breach of contract claim under New York law, a plaintiff must allege (1) the existence of an agreement, (2) sufficient performance of the contract by the plaintiff, (3) the defendant's breach of that contract, and (4) damages. Oberstein v. SunPower, Corp., 2010 WL 1705868 (E.D.N.Y. April 28, 2010)(citing Harsco Corp. v. Segui, 91 F.3d 337, 348 (2d Cir.1996)). To obtain specific performance of a contract, Plaintiff must establish that she was willing and able to perform her remaining obligations, that Defendant was able to perform its remaining obligations, and that there was no adequate remedy at law. Piga v. Rubin, 300 A.D.2d 68, 69 (1st Dept. 2002); Vertical Indus. Park Associates v. Hilco Real Estate, LLC, 19 Misc.3d 1117(A), 862 N.Y.S.2d 818 (Table) (N.Y.Sup. Ct. April 08, 2008); see also Five Star Development Resort Communities, LLC v. iStar RC Paradise Valley LLC, 2010 WL 2697137, at *4 (S.D.N.Y. July 06, 2010).¹⁸

"To succeed on a cause of action for specific performance or to recover damages for breach of contract, a plaintiff must establish, *inter alia*, the formation of a contract." W.J. Realty Corp. v. County of Suffolk, 901 N.Y.S.2d 674, 675-76 (2nd Dept. 2010).

Plaintiff alleges that, after discussing her participation in the clinical trial with Insmed CEO

¹⁸(specific performance is a remedy, not an independent claim)

Gunn, Insmmed's Study Manager O'Neil, and OSU's Amy Bartlett, and after being advised that Insmmed would support her compassionate use application if IPLEX proved to be helpful to her, she agreed to participate in the Insmmed-sponsored MMD1 trial. Compl. ¶¶ 119, 122-26, 129, 136, 141-46. She alleges that this participation benefitted Insmmed by providing it with data it could use to have IPLEX approved by the FDA, and that her participation was at a cost to her inasmuch as the trial required eight (8) twelve-hundred mile trips from Schenectady to OSU, painful and exhausting sessions to measure the effect of IPLEX on her, fastidious documentation of her condition, the risk she assumed in taking an untested drug, and detrimental physical consequences after abruptly stopping the use of IPLEX. Compl. ¶¶ 16, 33-41, 133-34, 146, 149, 117, 168-73. Plaintiff further alleges that she fulfilled all of her obligations under this agreement, and that Insmmed, without justification, refused to do the same. Compl. ¶¶ 167-68, 175-77, 179-180.

Plaintiff contends that she suffered damages as a result of the breach of contract, or a foreseeable consequence thereof, in the nature of her physical deterioration resulting from Insmmed's refusal to support of her compassionate use application thereby abruptly stopping her from taking IPLEX. Moreover, Plaintiff seeks specific performance in that she seeks an order requiring Defendant to support her compassionate use application and, if granted by the FDA, to provide her IPLEX at Defendant's cost.

Defendant argues that Plaintiff's breach of contract claim is barred by New York's Statute of Fraud rules because the contracts to which Plaintiff refer (*i.e.* the conversations between Plaintiff and Insmmed personnel (Gunn and O'Neil) & the conversation between Plaintiff and Bartlett) were oral in nature, not capable of being performed within one year, and/or involved the sale of goods with a value of \$500 or more. See N.Y. Gen. Oblig. Law

§ 5-701; N.Y. U.C.C. § 2-201. Defendant's Statute of Frauds arguments, at least at this stage of the proceedings, do not warrant dismissal of the breach of contract claim.

As to the one year requirement, Plaintiff's participation in the clinical trial was for a period of six (6) months from May 2008 through October 2008. Compl. ¶¶ 9, 116, 150. It is unclear from the Complaint when Plaintiff spoke to Gun or O'Neil regarding the compassionate use issue, although it is alleged that Plaintiff spoke with O'Neil about Plaintiff's participation in the phase IIB MMD1 trial on January 2, 2008. Compl. ¶ 126. A reasonable inference could be drawn that the conversation addressed Plaintiff's concern about a post-trial compassionate use application. Plaintiff also alleges that Bartlett, speaking with apparent authority to bind Insmed, advised her on April 7, 2008 that Insmed would support her compassionate use application if the IPLEX proved to be beneficial to Plaintiff. Compl. ¶¶ 141-44. From either January 2, 2008 or April 7, 2008, less than one year elapsed to the time that Plaintiff sought Defendant's support for her compassionate use application. While Defendant argues that the clinical trial proceeded longer than Plaintiff's participation in it and that the results of the trial could not be opened until the trial was concluded to determine whether Plaintiff was given IPLEX or a placebo, those facts cannot be determined from the Complaint. Thus, based on the allegations in the Complaint, the one year limitation period of the Statute of Frauds does not bar the claim.

By similar reasoning, the value of the IPLEX cannot be determined from the allegations of the complaint. Thus, to the extent that N.Y. U.C.C. § 2-201 is applicable in this case,¹⁹ it does not serve as the basis for dismissal at this stage of the proceedings.

¹⁹N.Y. U.C.C. § 2-201 applies to contracts for the sale of goods of \$500 or more.

Defendant also argues that the breach of contract claim must be dismissed because Plaintiff has not alleged damages caused by the asserted breach. The Court disagrees. To the extent the contract was for Defendant's support for Plaintiff's compassionate use application, and inasmuch as Plaintiff has asserted that she suffered progressively more intense physical detriment from the withdrawal of IPLEX following the end of the clinical trial, she has stated reasonably foreseeable damages arising from the purported breach. See Bi-Economy Mkt., Inc. v. Harleystown Ins. Co. of N. Y., 10 N.Y.3d 187, 192-94 (2008).²⁰ Furthermore, Plaintiff has stated a sufficient basis to seek specific performance. See Clearmont Property, LLC v. Eisner, 58 A.D.3d 1052, 1055 (3rd Dept. 2009). Accordingly, Defendant's motion to dismiss the Fourth Cause of Action is denied.

5. Intentional Infliction of Emotional Distress

Plaintiff's Fifth Cause of Action asserts a claim of intentional infliction of emotional distress arising from Defendant's failure to support her compassionate use application. Under New York law, the elements of an intentional infliction of emotional distress claim are: "(1) extreme and outrageous conduct; (2) intent to cause, or reckless disregard of a substantial probability of causing, severe emotional distress; (3) a causal connection

²⁰In Bi-Economy, the New York Court of Appeals noted that, under New York law, consequential damages are available in a breach of contract action where they are "brought within the contemplation of the parties as the probable result of a breach at the time of or prior to contracting." Bi-Economy, 10 N.Y.3d at 192 (quoting Kenford Co. v. County of Erie, 73 N.Y.2d 312, 319 (1989)). The Court explained further that a party "is liable for those risks foreseen or which should have been foreseen at the time the contract was made." Id. at 192-93 (quoting Ashland Mgt. v. Janien, 82 N.Y.2d 395, 403 (1993)). "To determine whether consequential damages were reasonably contemplated by the parties, courts must look to the nature, purpose and particular circumstances of the contract known by the parties ... as well as what liability the defendant fairly may be supposed to have assumed consciously, or to have warranted the plaintiff reasonably to suppose that it assumed, when the contract was made." Id. at 193 (interior quotation marks and citation omitted).

between the conduct and the injury; and (4) severe emotional distress." Stuto v. Fleishman, 164 F.3d 820, 827 (2d Cir. 1999). Such a claim requires an act "so outrageous in character, and so extreme in degree, as to go beyond all possible bounds of decency, and to be regarded as atrocious, and utterly intolerable in a civilized society." Howell v. New York Post Co., 81 N.Y.2d 115, 122 (1993)(interior quotation marks and citations omitted). Determining whether the alleged conduct is sufficiently outrageous to be actionable is a question of law for the Court. Holwell, 81 N.Y.2d at 122.

Viewing Defendant's failure to support Plaintiff's compassionate use application in the context in which it occurred, the decision does not rise to the level of the extreme and outrageous conduct necessary to support the claim. As Plaintiff alleges, IPLEX was not approved by the FDA and the clinical trials for the drug, including the phase of the trial Plaintiff participated in, had not been completed at the time Plaintiff sought support for her compassionate use application. Compl. ¶ 167. Further, according to Plaintiff, the representation was made that Insmmed would support her companionate use application only if IPLEX "proved to be safe and effective" for her. Compl. ¶ 144. She contends that when she first sought support for her compassionate use application, her request was denied because it had not been confirmed that she had been IPLEX as opposed to a placebo. Compl. ¶ 176. After she inquired a second time, she was advised that Insmmed determined that it would not be proceeding to Phase III of the clinical trial because it did not find a statistically significant improvement in symptoms of MMD1 patients. Compl. ¶ 177. Through communications with Bartlett and directly with Insmmed, Plaintiff was advised that "the clinical trial design for the study in which you participated does not allow for open extension use (compassionate use)" and that "there is no mechanism for Insmmed

to provide IPLEX to you.” Compl. ¶ 180; see id. ¶179.

Based on these allegations, the Court does not find that Defendant’s decision, apparently based on its review of the clinical, scientific, and administrative factors involved in a compassionate use application for IPLEX to a patient with MMD1, does not amount to conduct “so outrageous in character, and so extreme in degree, as to go beyond all possible bounds of decency, and to be regarded as atrocious, and utterly intolerable in a civilized society.” Howell, 81 N.Y.2d at 122. While the decision may be unfair, in breach of an agreement, or without a rational basis, it is not sufficiently outrageous to be actionable. Accordingly, the claim asserting the intentional infliction of emotional distress is dismissed.

6. Assumption of Duty

Plaintiff’s Sixth Cause of Action asserts a claim of assumption of duty. Plaintiff contends that Defendant’s conduct and representations caused her to forgo other opportunities to relieve her MMD1 symptoms. Compl. ¶¶ 207-10.

“[A]n assumed duty . . . may arise once a person undertakes a certain course of conduct upon which another relies. In determining whether a cause of action lies in such instances, the query always is whether the putative wrongdoer has advanced to such a point as to have launched a force or instrument of harm, or, rather, whether he or she has merely stopped where inaction is at most a refusal to become an instrument of good. Put differently, the question is whether defendant’s conduct placed plaintiff in a more vulnerable position than plaintiff would have been in had defendant done nothing.

Heard v. City of New York, 82 N.Y.2d 66, 72 (1993)(interior quotation marks and citations omitted). Further, there must be a demonstration that Plaintiff’s reliance on Defendant’s conduct is what placed Plaintiff in a more vulnerable position than she would otherwise have been in had the defendant done nothing. Falu v. 233 Assoc., 258 A.D.2d 342, 343 (1st Dept. 1999).

As Plaintiff alleges, there is no approved treatment for the cause of MMD1. Compl. ¶¶ 8, 31. Because IPLEX seemed to Plaintiff to be the only drug that improved the symptoms of her MMD1, and because she could not obtain the IPLEX without a compassionate use grant by the FDA, she has pursued this action seeking Defendant's assistance in her compassionate use application. Even though Plaintiff has alleged that the sudden stop of the IPLEX caused a rapid deterioration of her physical condition to a state more disabling than her pre-trial condition, she seeks to compel Defendant to support her compassionate use application so that she can use the drug in the future. Thus, accepting Plaintiff's contentions as true, she has plead merely that Defendant "stopped where inaction is at most a refusal to become an instrument of good." She has not alleged facts that plausibly demonstrate that Defendant's promise to support her compassionate use application enhanced the risk that Plaintiff faced, created a new risk, or induced Plaintiff to forego some other unidentified, unknown, or unproven opportunity to avoid risk. Accordingly, Plaintiff's claim of breach of the assumption of duty is dismissed.

7. Breach of Fiduciary Duty

Plaintiff's Seventh Cause of Action asserts that Defendant breached a fiduciary duty owed to her. In this regard, she alleges that, by virtue of the fact that Defendant was an "expert in the field of pharmaceutical research" and that, based on the "its control and direction over the transaction it entered into with Plaintiff," Plaintiff was "induced to trust Defendant to look out for her interests within the confines of her IPLEX treatment." Compl. ¶ 212. Plaintiff asserts that Defendant breached its fiduciary duty by failing to support her compassionate use application. *Id.* ¶ 213.

"A fiduciary relationship 'exists between two persons when one of them is under a

duty to act for or to give advice for the benefit of another upon matters within the scope of the relation.” EBC I, Inc. v Goldman, Sachs & Co., 5 N.Y. 3d 11, 19 (2005)(quoting Restatement [Second] of Torts § 874, Comment a)). “Essential elements of a fiduciary relation are . . . reliance, . . . *de facto* control and dominance. Stated differently, a fiduciary relation exists when confidence is reposed on one side and there is resulting superiority and influence on the other.” AG Capital Funding Partners, L.P. v. State Street Bank and Trust Co., 11 N.Y. 3d 146, 158 (2008)(interior citation marks and citations omitted).

Here, there was no fiduciary duty on Defendant’s part to administer and monitor the effects of IPLEX during the clinical trial, see Abney v. Amgen, Inc., 443 F.3d 540, 551 (6th Cir. 2006);²¹ Suthers v. Amgen, Inc., 372 F. Supp. 2d 416, 426 (S.D.N.Y. 2005), and there are insufficient facts plausibly demonstrating that Insmed had a fiduciary duty relative to any treatment Plaintiff would or could receive after the clinical trial concluded. According, the breach of fiduciary duty claim is dismissed.

8. Negligence

The Eighth Cause of Action asserts a claim of common law negligence. Compl. ¶¶ 215-17. Plaintiff alleges that Insmed negligently, recklessly, and/or intentionally breached a general duty of care owed to her when it refused to support her compassionate use application and thereby “forced her into a rapid and dangerous withdrawal from IPLEX.” PI. MOL p. 28; see Compl. ¶ 216. Plaintiff fails to assert facts that plausibly support a claim of negligence. “While a complaint attacked by a Rule 12(b)(6) motion to dismiss

²¹(under FDA regulations, a clinical trial’s Institutional Review Board, not the sponsoring pharmaceutical company, is charged with ensuring trial participants’ well being during the trial)

does not need detailed factual allegations . . . a plaintiff's obligation to provide the 'grounds' of [her] 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Twombly, 127 S. Ct. at 1964-65. Plaintiff has done little more than provide labels and conclusions in support of her negligence claim. Therefore, the claim is dismissed.

9. Unjust Enrichment

To prevail on an unjust enrichment claim under New York law, a plaintiff must demonstrate "(1) that the defendant benefitted, (2) at the plaintiffs expense, and (3) that equity and good conscience require restitution." Nordwind v. Rowland, 584 F.3d 420, 434 (2d Cir. 2009)(citation omitted). "Unjust enrichment "rests upon the equitable principle that a person shall not be allowed to enrich himself unjustly at the expense of another . . . The general rule is that the plaintiff must have suffered a loss and an action not based upon loss is not restitutionary." State v. Barclays Bank of New York, 76 N.Y.2d 533, 540-541 (1990)(interior quotation marks and citation omitted); see also Old Republic Natl. Title Ins. Co. v. Luft, 52 AD 3d 491, 491-92 (2d Dept. 2008).

While Plaintiff alleges that Defendant was benefitted by her participation in the clinical trial in the sense that Defendant received the results of her IPLEX use, the allegations in the Complaint establish that she willfully entered the clinical trial and that she received the benefit of the IPLEX during her participation. Plaintiff fails to plausibly allege that she suffered a loss to Defendant for which Defendant should pay restitution. Accordingly, the unjust enrichment claim is dismissed.

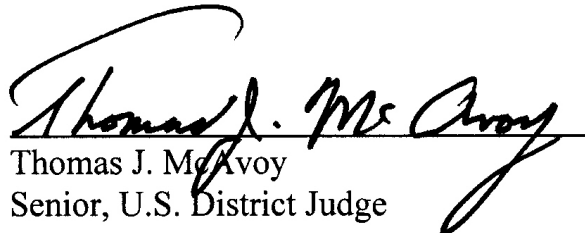
IV. CONCLUSION

For the reason discussed above, Defendant's motion to dismiss [dkt. # 30] is

GRANTED IN PART and DENIED IN PART. In this regard, Plaintiff's 1st (violation of constitutional right to equal protection), 5th (intentional infliction of emotional distress), 6th (assumption of duty), 7th (breach of fiduciary duty), 8th (negligence), and 9th (unjust enrichment) Causes of Action are **DISMISSED**. The motion is denied in all other respects.

IT IS SO ORDERED

DATED: June 29, 2011


Thomas J. McAvoy
Senior, U.S. District Judge